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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,729	05/27/2005	Michael Barry Gravestock	100859-1P US	4310
44992	7590	06/09/2006	EXAMINER	
ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 06/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/536,729		GRAVESTOCK ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Yong Chu		1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,5-9,11-13, 15 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-9,11-13,18 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 5,6,13,18 and 20-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 0227701.0.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date: _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/27/2005</u>                                                             | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

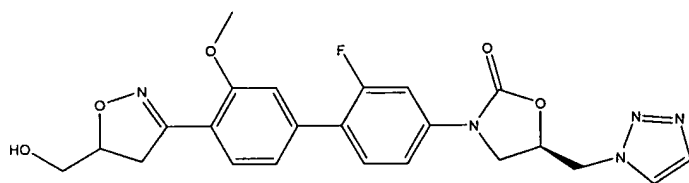
Claims 2-4, 10, 14, and 16-17 are cancelled by amendment filed on 15 May 2006. Claims 1, and 5-6 are amended by amendment filed on 15 May 2006. Therefore, Claims 1, 5-9, 11-13, 15, and 18-23 are currently pending in the instant application.

### *Priority*

This application is a 371 of PCT/GB03/05082, filed on 24 November 2003. Applicants claim the benefit of for U. K. Patent Application 0227701.0 filed on 28 November 2002, under 35 U.S.C. §119(a-d).

### *Response to Restriction*

Amendment filed by Applicant's Representative Heidi Berven on 15 May 2006 has been considered. An election was made with traverse to **Group I**: Claims 1, 5-9, 11-13, 18, and 20-23 and the specific compound



of Example 3 is acknowledged.

As previously stated in the restriction requirement, in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims and method of use claims commensurate in scope with the allowed

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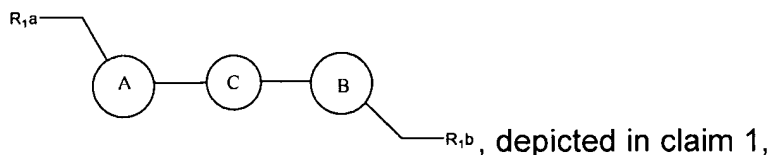
product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

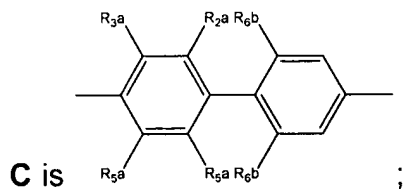
### ***Status of the Claims***

The scope of the invention of the elected subject matter is as follows:

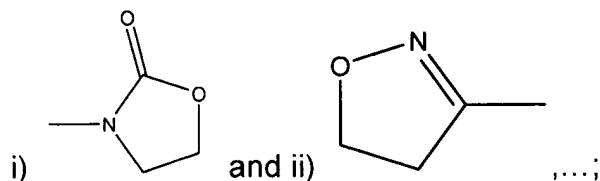
Compounds of formula (I),



wherein:



**A** and **B** are independently selected from



**R<sub>2b</sub>** and **R<sub>6b</sub>** are independently selected from H, F, Cl, -OMe, Me, Et, and -CF<sub>3</sub>;

The rest substituents are defined as in Claim 1 of the Amendment file on May 15, 2006.

As a result of the election and the corresponding scope of the invention identified supra, Claims 15, 19, and the remaining subject matters of claims 1, 5-9, 11-13, 18, and 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Therefore, Claims 1, 5-9, 11-13, 18, and 20-23 are ready for examining.

### ***Claim Rejections - 35 USC § 102***

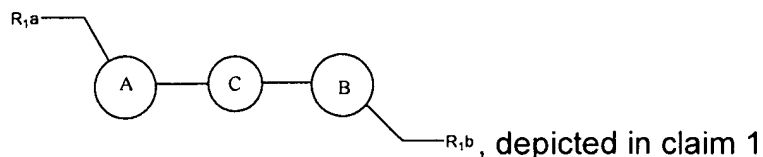
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 11-13, 18, and 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gravestock et al. **WO 03/022824**.

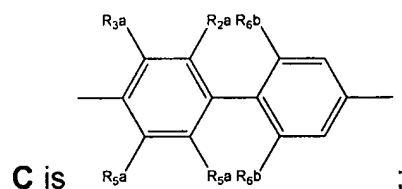
The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants instant elected invention in Claims 1, 5-9, 11-13, 15, 18, and 20-23

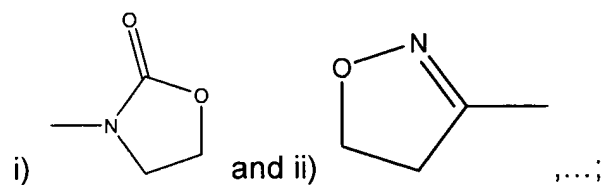
teaches compounds of formula (I)



of the amendment dated on May 15, 2006, their pharmaceutically acceptable salts and their pharmaceutical compositions thereof wherein:



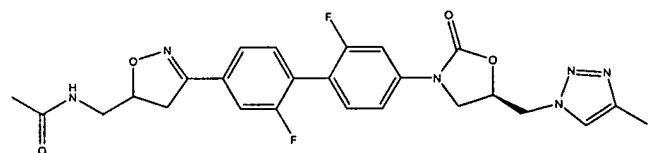
**A** and **B** are independently selected from



**R<sub>2b</sub>** and **R<sub>6b</sub>** are independently selected from H, F, Cl, -OMe, Me, Et, and -CF<sub>3</sub>;

The rest substituents are defined as in Claim 1 of the Amendment file on May 15, 2006.

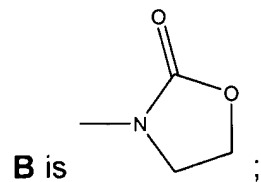
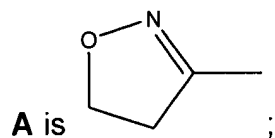
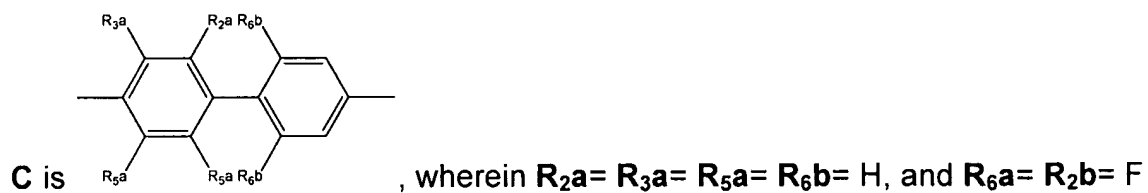
Gravestock et al. teach specific compounds of Example 16

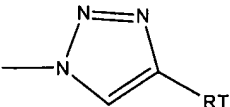


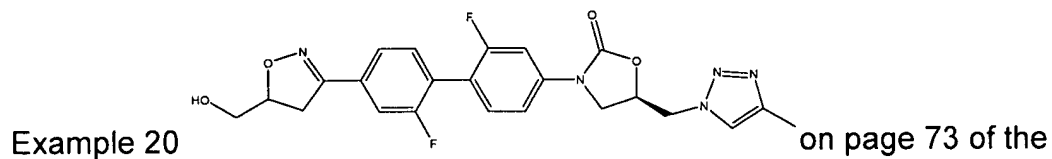
of page 67 of the Specification, read on

the instant claims 1, 7-9, 11, 13, 18, and 20-23 wherein:

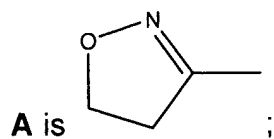
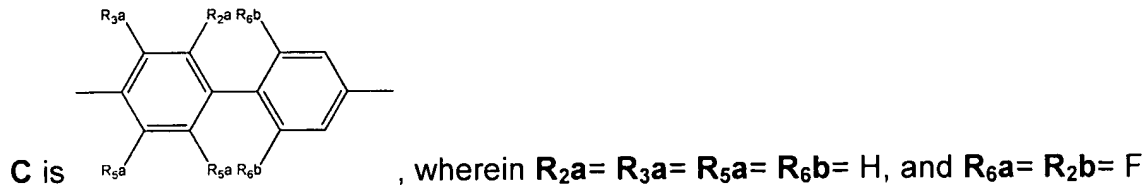
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 $R_{1a}$  is  $-NHCOCH_3$ ;

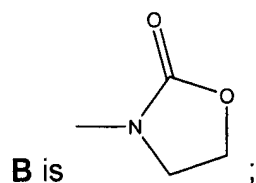
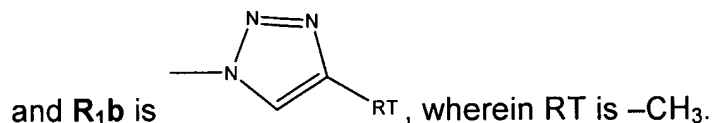
and  $R_{1b}$  is , wherein RT is  $-CH_3$ .



Specification, read on the instant claims 1, 7-9, 11, 13, 18, and 20-23 wherein:



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**R<sub>1a</sub>** is -OH;

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

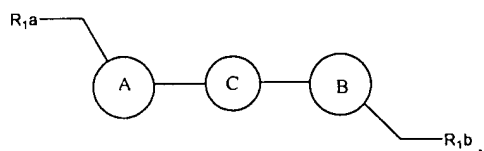
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-9, 11-12, and 18 provisionally rejected on the ground of nonstatutory double patenting over claims 1-13, and 17 of copending Application No. 10/489,266.



Claims 1, 7-9, 11-12, and 18 provisionally rejected on the ground of nonstatutory double patenting over copending Application No. 10/536,686, and 10/539,482. These are provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The compounds and their pharmaceutical formulations of the compounds with formula



, wherein the substituents are defined in Claim 1 of the three co-pending applications.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804. A terminal Disclaimer may need to overcome the Double Patenting rejection.

### ***Claim Objections***

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. Claim 13 is duplicate of art of Claim 1 without further limiting.

Claims 5-6, 18, and 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

No claims are allowed.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Yong Chu, Ph.D.  
Patent Examiner  
Art Unit 1626



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